

DRAFT
ENGINEERING EVALUATION
Bayer HealthCare – Pharmaceuticals, Inc.
APPLICATION NO. 15256

BACKGROUND

Bayer HealthCare – Pharmaceuticals, Inc. (Bayer) is applying for an Authority to Construct and/or to Permit to Operate the following equipment:

- S-1 Solvent Cleaning at Buildings D and M**
S-2 Solvent Cleaning at Building PDM

Bayer cleans surfaces for the manufacture of vaccines. Bayer uses either a solution of 70% isopropanol and 30% water or 70% ethanol and 30% water to clean surfaces.

EMISSIONS SUMMARY

Annual Emissions:

Bayer will use up to 630 gallons per year of isopropanol or ethanol cleaning solution at each S-1 and S-2 Solvent Cleaning. The cleaning solutions are 70% solvent and 30% water. For a conservative estimate of emissions, the solvent with the higher density will be used to calculate emissions. Assume 100% of the solvent in the solution is emitted into the atmosphere.

Isopropyl Alcohol (POC)	6.53 lb/gal
Ethanol (POC)	6.61 lb/gal

$$\begin{aligned}\text{S-1 POC emissions} &= (630 \text{ gal/yr})(0.70 \text{ solvent})(6.61 \text{ lb/gal}) = 2,915 \text{ lb/yr} = 1.46 \text{ tpy} \\ \text{S-2 POC emissions} &= (630 \text{ gal/yr})(0.70 \text{ solvent})(6.61 \text{ lb/gal}) = 2,915 \text{ lb/yr} = 1.46 \text{ tpy}\end{aligned}$$

$$\text{Total increase in POC emissions} = 2,915 \text{ lb/yr} + 2,915 \text{ lb/yr} = 5,830 \text{ lb/yr} = 2.92 \text{ tpy}$$

Maximum Daily Emissions:

Bayer operates 24 hrs/day, 7 days/wk, and 52 wks/yr.

$$\begin{aligned}\text{S-1 Daily Maximum POC Emission} &= (2,915 \text{ lb/yr}) / (7 \text{ days/wk} \times 52 \text{ wks/yr}) = 8.0 \text{ lb/day} \\ \text{S-2 Daily Maximum POC Emission} &= (2,915 \text{ lb/yr}) / (7 \text{ days/wk} \times 52 \text{ wks/yr}) = 8.0 \text{ lb/day}\end{aligned}$$

Plant Cumulative Increase: (tons/year):

Pollutant	Existing	New	Total
NOx	0	0	0
POC	0	2.92	2.92
CO	0	0	0
SO2	0	0	0
PM10	0	0	0
NPOC	0	0	0

Toxic Risk Screening:

Bayer may use at most 630 gallons of isopropanol or ethanol solvent solution at each S-1 and S-2 Solvent Cleaning. Ethanol does not appear on the District Toxic Air Contaminant List of Table 2-5-1.

Toxic Pollutant	Emission Rate*		Risk Screening Trigger	
			Acute	Chronic
Isopropanol	0.66 lb/hr	5,760 lb/yr	7.1 lb/hr	270,000 lb/yr

* Based on the use 1,260 gallons of a 70% isopropanol solution 24 hrs/day, 7 days/wk, and 52 wks/yr.

The use of isopropanol by Bayer is substantially below the toxic air contaminant trigger level and a Risk Screening Analysis is not required.

STATEMENT OF COMPLIANCE

Solvent cleaning at S-1 and S-2 requires the wiping down of manufacturing and laboratory surfaces at Bayer. The owner/operator is exempt from Regulation 8, Rule 16: Organic Compounds: Solvent Cleaning Operations per Regulation 8-16-111: Exemption, Wipe Cleaning. The owner/operator is subject to Regulation 8, Rule 4: Organic Compounds, General Solvent and Surface Coating Operations. The owner/operator will emit up to 1.793 tons per year of VOCs at each S-1 and S-2. The emissions are well below the limit of 5 tons per year in Regulation 8-4-302.1. The owner/operator shall meet the solvent evaporative loss minimization requirements of Regulation 8-4-312. The owner/operator shall use closed containers for the storage or disposal of cloth or paper used for solvent surface preparation and cleanup. The owner/operator shall close containers of solvent when not in use. Bayer is not subject to the solvent VOC limit of 50 g/l (0.42 lbs/gal) or the overall VOC control and abatement efficiency of 85% in Regulation 8-4-313 Solvent Preparation Standards. Bayer is a medical device and pharmaceutical manufacturer per Regulation 8-4-225 and is exempt from Regulation 8-4-313 per Regulation 8-4-116 Limited Exemption, Specific Surface Preparation and Cleaning Operations. The owner/operator will be subject to the recordkeeping requirements of Regulation 8-4-501.

The project is considered to be ministerial under the District's CEQA regulation 2-1-311 and therefore is not subject to CEQA review. The engineering review for this project requires only the application of standard permit conditions and standard emissions factors and therefore is not discretionary as defined by CEQA. (Permit Handbook Chapter 6.3)

The project is within 1000 feet of Pacific Rim School (K-6th Grade) and within ¼ mile of Emery Secondary School and is therefore subject to the public notification requirements of Reg. 2-1-412. Bayer has purchased and will take over the manufacturing of multiple sclerosis drugs from Novartis Vaccines Diagnostics, Inc. (Novartis) in Emeryville. Bayer will own and operate the manufacturing operations for the multiple sclerosis drugs, while Novartis will continue to own and operate its research and manufacturing of other drugs at the 4560 Horton Street facility. Both Bayer and Novartis have each applied for two solvent cleaning sources. This engineering evaluation for application 16256 covers the solvent cleaning sources for Bayer while the engineering evaluation for application 16257 addresses to the two solvent cleaning sources for Novartis. Since both companies are located at the same location and address and since both applicants are applying for permits to operate similar sources with the same solvents, one public notice will be prepared for both applicants (Novartis and Bayer) and applications (16256 and 16257). A public notice will be prepared and sent to:

All addresses within 1000 feet of the solvent cleaning sources
Parents and guardians of students at the Pacific Rim School and Emery Secondary School

All comments received during the 30-day comment period will be addressed.

Best Available Control Technology: In accordance with Regulation 2, Rule 2, Section 301, BACT is triggered for any new or modified source with the potential to emit 10 pounds or more per highest day of POC, NPOC, NO_x, CO, SO₂ or PM₁₀. Based on the emissions calculations above, the owner/operator is not subject to BACT.

Offsets: Offsets must be provided for any new or modified source at a facility that emits more than 10 tons/yr of POC or NO_x per Regulation 2-2-302. The District may provide offsets from the Small Facility Banking Account for a facility with emissions between 10 and 35 tons/yr of POC or NO_x, provided that facility has no available offsets. Based on the emission calculations above, no offsets of POC are required.

PSD, NSPS, and NESHAPS do not apply.

PERMIT CONDITIONS

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- S-1 Solvent Cleaning at Buildings D and M
- S-2 Solvent Cleaning at Building PDU

1. At each of the solvent cleaning sources, S-1 and S-2, the owner/operator shall not use more than 630 gallons of cleaning solution containing 70% solvent (isopropyl alcohol or ethanol) in any consecutive 12-month period.
(basis: Cumulative increase)
2. Solvents other than the material specified in part 1, and/or usages in excess of that specified in part 1, may be used provided that the owner/operator can demonstrate that the following are satisfied:
 - a. Total POC emissions from S-1 or S-2 do not exceed 2,915 lbs. per source in any consecutive 12-month period.
 - b. The use of these materials does not increase toxic emissions above any risk screening trigger level.
(basis: Cumulative increase)
3. In order to minimize solvent losses, the owner/operator shall use only controlled flow solvent dispensers (e.g., squeeze bottles) to dispense solvent for wipe cleaning. In addition, the owner/operator must keep all solvent impregnated cloths or papers not in active use in closed containers.
(basis: Regulation 8-4-312)
4. To determine compliance with the above conditions, the owner/operator shall maintain the following records and provide all of the data necessary to evaluate compliance with the above conditions, including, but not necessarily limited to, the following information:
 - a. Record on a monthly basis the type, amount, and POC content of each cleanup solvent used.
 - b. If a material other than those specified in part 1 is used or a material specified in part 1 is used in excess of the limit in part 1, POC and toxic component contents of each material used; and mass emission calculations to demonstrate compliance with part 2, on a monthly basis.
 - c. Monthly usage and/or emission calculations shall be totaled for each consecutive 12-month period.

The owner/operator shall record all records in a District-approved log. The owner/operator shall retain all records on-site for two years, from the date of entry, and make them available for inspection by District staff upon request. These record-keeping requirements shall not replace the record-keeping requirements contained in any applicable District Regulations.

(basis: Cumulative Increase, Recordkeeping Regulation 8-4-501)

RECOMMENDATION

Issue a Permit to Operate to Bayer HealthCare – Pharmaceuticals, Inc. for the following equipment:

S-1 Solvent Cleaning at Buildings D and M

S-2 Solvent Cleaning at Building PDU

EXEMPTIONS

None

By: _____
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